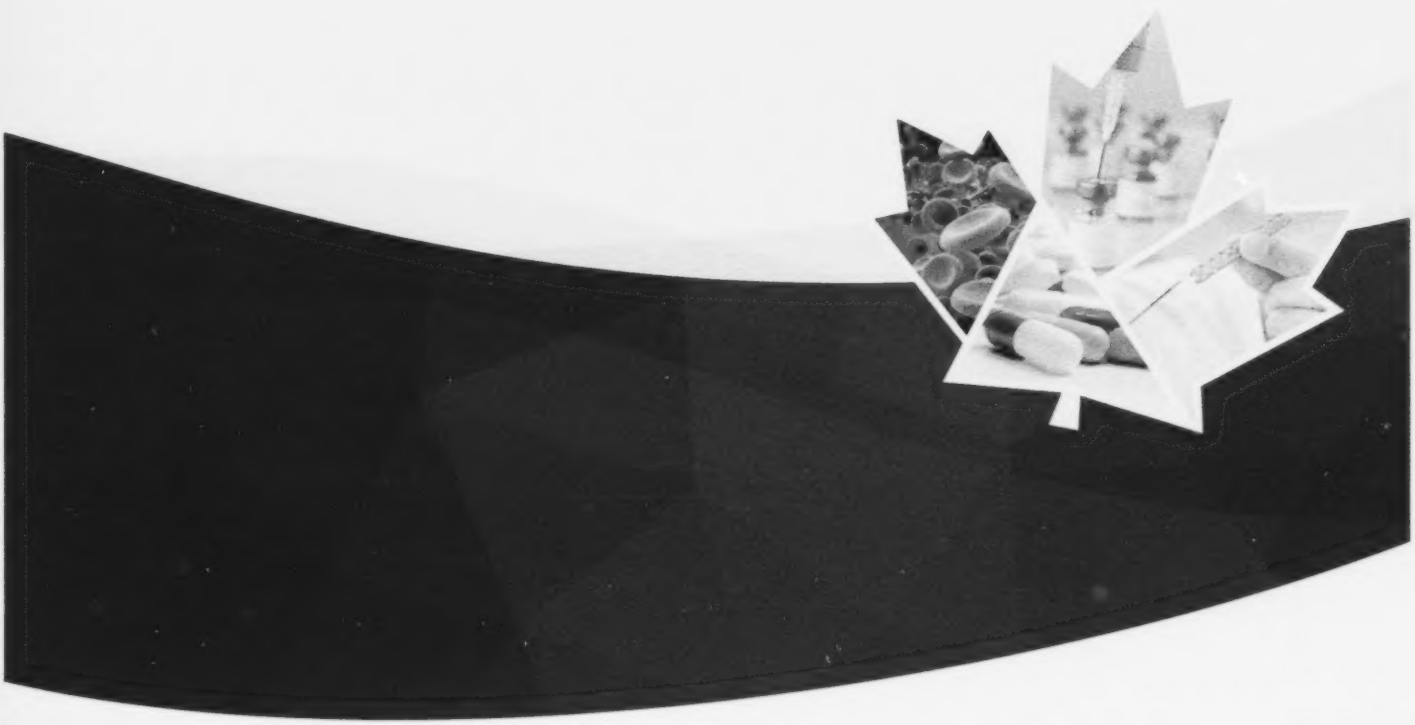
Health Canada Santé Canada

Guidance Document

Patented Medicines (Notice of Compliance) Regulations

Date Adopted: 2000/02/14
Revised Date: 2018/04/05
Effective Date: 2018/05/11



Canada

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

Également disponible en français sous le titre :
Ligne directrice : Règlement sur les médicaments brevetés (avis de conformité)

To obtain additional information, please contact:

Health Canada
Address Locator 0900C2
Ottawa, ON K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
E-mail: publications@hc-sc.gc.ca

© Her Majesty the Queen in Right of Canada, as represented by the Minister of Health, 2018

Publication date: May 2018

This publication may be reproduced for personal or internal use only without permission provided the source is fully acknowledged.

Cat.: H13-9/11-2018E-PDF
ISBN: 978-0-660-26153-9
Pub.: 170559

Foreword

Guidance documents are meant to provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document may be acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

Document change log

Date: 2018/04/05

Change: Updated in accordance with the September 21, 2017 amendments to the Patented Medicines (Notice of Compliance) Regulations.

Location (section, paragraph): All

Nature of and/or reason for change: The updates to the Guidance Document are being made following the amendments to the Patented Medicines (Notice of Compliance) Regulations, which came into force on September 21, 2017. The updates also reflect current administrative practices (e.g. update of terminology from "patent hold" to "intellectual property hold").

Table of Contents

1. Introduction 7
   1.1 Policy objectives 7
   1.2 Policy statements 7
   1.3 Scope and application 7
   1.4 Background 7

2. Definitions 7

3. General information 8
   3.1 General 8
   3.2 Patent Register 8
   3.3 Drug Identification Number (DIN) cancellation - deletion of Patent Lists from the Patent Register 8
   3.4 How to provide information to the TPD 8
      3.4.1 How to provide litigation information 8
      3.4.2 How to provide other information 10

4. Section 4 of the PM(NOC) Regulations 10
   4.1 General 10
   4.2 Timing requirements 11
      4.2.1 Patent Lists at time of filing a submission 11
      4.2.2 Patent Lists after time of filing a submission 11
   4.3 Content requirements and prioritisation 11
   4.4 Drug submissions eligible for filing a Patent List 11
   4.5 Product specificity requirements 12
      4.5.1. Patent List in relation to a New Drug Submission 12
      4.5.2 Patent List in relation to a Supplement to a New Drug Submission 13
      4.5.3 Carry-forward provision 14
      4.5.4 Consultation 14
   4.6 Process 14
   4.7 Certificates of Supplementary Protection 15
      4.7.1 Process 16
   4.8 Addition of patent(s) and CSP(s) to the Patent Register 16
   4.9 Accuracy of Patent List information 17
   4.10 Re-issued patents 17

5. Section 5 of the PM(NOC) Regulations 17
   5.1 Scope and application of Section 5 17
      5.1.1 Administrative drug submissions 18
   5.2 Submission of a Form V: Declaration re: Patent List 19
   5.3 Freezing the Patent Register: addressing additions to the Patent Register on or after the date of filing of a second person's submission or supplement 19
   5.4 Certification of date of filing 20
   5.5 Deemed date of filing under Canada's Access to Medicines Regime 20
   5.6 Notice of Allegation and information to be served on a First Person 21
      5.6.1 Timing of service 21
      5.6.2 Contents of Notice of Allegation and documents served with a Notice of Allegation 21
      5.6.3 Information to provide to the TPD 21
      5.6.4 Retraction of a Notice of Allegation 21
   5.7 Second Person company name changes prior to NOC issuance 22

6. Sections 6 and 7 of the PM(NOC) Regulations 22
   6.1 Actions 22

6.2 Intellectual property hold 22
6.3 NOC issuance to a Second Person in the absence of an action for patent infringement 22
6.4 Verification of portions of a submission or supplement 23
6.4.1 Verification process 23
6.5 Consent 24
6.6 Renouncing the 24-month stay 24

7. Maintenance of the Patent Register 24

Appendices 25
Appendix A - How to complete a Form IV: Patent List 25
Appendix B - How to complete a Form V: Declaration re Patent List 27
Appendix C - Sample productions for verification 29

1. Introduction

1.1 Policy objectives

In accordance with the Regulatory Impact Analysis Statement (RIAS) published in the Canada Gazette, Part II on October 18, 2006,[1] Canada's pharmaceutical patent policy objective is to "balance the effective patent enforcement over new and innovative drugs with the timely entry of their lower priced generic competitors". The Patented Medicines (Notice of Compliance) Regulations (PM(NOC) Regulations) were introduced originally by Industry Canada (now known as Innovation, Science and Economic Development Canada) under the Patent Act. The PM(NOC) Regulations intersect with drug approval under the Food and Drugs Act and Division 8 of the Food and Drug Regulations.

1.2 Policy statements

The early working exception of subsection 55.2(1) of the Patent Act allows a subsequent manufacturer to use a patented invention for the purpose of seeking regulatory approval of that product. The provision, therefore, provides an exception from infringement. The PM(NOC) Regulations provide the balance, through a patent enforcement mechanism, to ensure that the early working exception is not abused by linking the regulatory approval of a generic drug to the patent status of the innovative product.

1.3 Scope and application

This guidance document provides information regarding the administration of the PM(NOC) Regulations by the Office of Patented Medicines and Liaison (OPML) within the Office of Submissions and Intellectual Property (OSIP), Therapeutic Products Directorate (TPD), Health Canada. It is applicable to drugs that receive a notice of compliance (NOC), including pharmaceutical, biological, radiopharmaceutical and veterinary drugs.

1.4 Background

The PM(NOC) Regulations were originally enacted in 1993, and have undergone various amendments. The most recent amendment came into force on September 21, 2017. Under the pre-2017 version of the PM(NOC) Regulations, innovative drug companies could commence legal proceedings for an order prohibiting the Minister of Health from granting a notice of compliance for a generic version of a patented medicine. The September 21, 2017 amendments to the PM(NOC) Regulations replaced these prohibition application proceedings with full actions resulting in final determinations of patent infringement and validity. The pre-2017 version of the PM(NOC) Regulations will continue to apply in respect of any matter that relates to a notice of allegation served on a first person before September 21, 2017.

2. Definitions

Filing date of a submission

Refers to the date that the submission is deemed administratively complete by Health Canada (i.e. once all elements and forms required for processing are completed and submitted to Health Canada). This date may differ from the date of original receipt should the submission be considered administratively incomplete at the time of receipt. The filing date established for a submission is not affected by subsequent screening or review activities. In the Drug Submission Tracking System - Industry Access, the filing date of a submission is indicated in the field "CR Date".

---

[1] Canada Gazette 2006.II.1510.

Filing date of a patent

Refers to the Canadian filing date of a Canadian patent application as established by the Canadian Intellectual Property Office.

Patent

Refers to a granted Canadian patent (not a patent application).

Biosimilar biologic drug

Refers to a biologic drug that obtains market authorization subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug. A biosimilar relies in part on prior information regarding safety, efficacy and effectiveness that is deemed relevant due to the demonstration of similarity to the reference biologic drug and which influences the amount and type of original data required. Biosimilar biologic drugs were previously referred to as Subsequent Entry Biologics.

3. General information

3.1 General

The OPML within OSIP, TPD administers the PM(NOC) Regulations. All drug submissions seeking a NOC, including those submitted to the Biologics and Genetic Therapies Directorate (BGTD), Natural and Non-Prescription Health Products Directorate (NNHPD) and Veterinary Drugs Directorate (VDD), are assessed to determine if they fall within the scope of the PM(NOC) Regulations. The directorates mentioned above are a part of Health Canada's Health Products and Food Branch (HPFB).

3.2 Patent Register

Pursuant to subsection 3(2) of the PM(NOC) Regulations, the TPD is required to maintain a register of patents that have been submitted for addition to the register and certificates of supplementary protection in which any of those patents are set out.

The Patent Register is available online (http://pr-rdb.hc-sc.gc.ca/pr-rdb/index-eng.jsp) and is refreshed nightly. Any questions, comments or problems with the Patent Register should be directed to the Office of Patented Medicines and Liaison (hc.opml-bmbl.sc@canada.ca).

3.3 Drug Identification Number (DIN) cancellation - deletion of Patent Lists from the Patent Register

Subsection 3(3) of the PM(NOC) Regulations applies to drugs for which the drug identification number (DIN) has been cancelled under the Food and Drug Regulations. As provided for in subsection 3(3), patents added to the Patent Register in respect of a drug for which the DIN was cancelled shall be deleted from the Patent Register by the TPD 90 days after the DIN was cancelled. An exception to this rule exists for cancellations effected as a result of a change in manufacturer.

Patent lists deleted as a result of a DIN cancellation will be re-added to the Patent Register upon re-activation of the DIN, i.e. receipt of a DIN Notification Form, as required by section C.01.014.3 of the Food and Drug Regulations. A first person who submits such a DIN Notification Form should also notify the OPML.

3.4 How to provide information to the TPD

3.4.1 How to provide litigation information

As the Minister of Health will not be a party to actions for patent infringement under the amended PM(NOC) Regulations, litigation documents in such actions will no longer be served on the Minister. However, the TPD must have access to relevant information to determine whether there are any barriers under the PM(NOC)

Regulations that would prohibit issuance of a NOC for a second person's submission. As such, under section 6.13 of the amended PM(NOC) Regulations, a person who brings an action for infringement is to provide the TPD with certain documents as soon as feasible. The TPD may also request any information or document required to assess whether NOC issuance is prohibited under section 7 of the PM(NOC) Regulations. Requests for verification of any portion of a submission served with a notice of allegation or produced in the course of a court action can be made under section 6.05 of the PM(NOC) Regulations.

All information related to litigation, including requests for verifications, must be submitted to the TPD electronically and no duplicate copy should be sent in paper format. Please provide the information by email to: hc.opml-bmbl.sc@canada.ca, or on an acceptable media format, using the requirements outlined below. As with other drug submission information submitted electronically, any information received after 5:00 pm Eastern Standard Time, on a weekend, or on a Statutory Holiday will be considered received on the next business day.

By email

Litigation information should be provided via email unless it exceeds the size limit, in which case it should be provided on media.

- The sender assumes the risk of transmitting confidential or sensitive information through email.
- The maximum email size accepted by the corporate mail server is 20 megabytes. Anything larger should be sent on media.
- Documents contained in the email should not be password protected.
- Please indicate PM(NOC) Regulations, the court file number and the stakeholder name in the subject line of the email.

On media

Electronic media may be sent by courier / mail.

- The media formats acceptable when providing information are:
  - Compact Disc-Recordable (CD-R) conforming to the Joliet specification
  - Digital Versatile Disc-Random Access Memory (DVD-RAM) Universal Disc Format (UDF) standard
  - Single and dual layer Recordable Digital Versatile Discs
  - Universal Serial Bus (USB) 2.0 or 3.0 drive
- Media and files should not be password protected
- Files stored on the media should not be zipped
- All information should be provided on a single disc/drive
- Media should be scanned using current virus-scanning software and should be certified virus-free
- All media should be labelled. The label on the disc/drive should contain the following information:
  - PM(NOC) Regulations
  - Stakeholder name
  - Court file number
  - "This media has been virus-scanned and we certify that it is virus free"
- Subsequent to burning the CD/DVD or transferring data to a drive, stakeholders should ensure that all files can be opened and no files are corrupt

- Information provided on approved media formats should be sent to the below address, to the attention of the OPML:

  Office of Submissions and Intellectual Property
  Therapeutic Products Directorate
  Health Products and Food Branch
  Health Canada
  Finance Building
  101 Tunney's Pasture Driveway
  Address Locator: 0201A1
  Ottawa, Ontario
  K1A 0K9

3.4.2 How to provide other information

As is currently required, other information related to the PM(NOC) Regulations should be submitted in either the electronic Common Technical Document (eCTD) format or the non-eCTD electronic-only format in module 1.2.4.1 - Patent Information. In accordance with Health Canada's Guidance Document: Preparation of Drug Regulatory Activities in the Electronic Common Technical Document Format and the Questions and Answers - Regulatory Activities in eCTD Format, regulatory transactions accepted in the eCTD format include:

- Written correspondence related to the PM(NOC) Regulations
- Notice of allegation packages (e.g. proof of service of the notice of allegation on the first person and a copy of the notice of allegation) under the PM(NOC) Regulations
- Form IVs, including updates, filed in accordance with the PM(NOC) Regulations
- Form Vs, including updates, filed in accordance with the PM(NOC) Regulations, and
- Consent letters (under the PM(NOC) Regulations)

For eCTD submissions, the regulatory transactions listed above should be submitted via the Common Electronic Submissions Gateway, as indicated in the Frequently Asked Questions - Common Electronic Submissions Gateway. For non-eCTD submissions, the above-noted information should be sent on an acceptable media format as indicated in the Guidance Document: Preparation of Drug Regulatory Activities in the 'Non-eCTD Electronic-Only' Format.

As with other drug submission information submitted electronically, any information received after 5:00 pm Eastern Standard Time, on a weekend, or on a Statutory Holiday will be considered received on the next business day.

4. Section 4 of the PM(NOC) Regulations

4.1 General

The requirements that must be met before a patent can be added to the Patent Register are provided by section 4 of the PM(NOC) Regulations. Section 4 describes (i) the timing requirements for filing patent lists; (ii) the required content of patent lists; (iii) the drug submissions for which patent lists may be filed; and (iv) eligibility requirements relating to the claims of the patent. The following sections provide more detailed guidance regarding these requirements.

A patent list must be submitted using the Form IV: Patent List template, available on the Health Canada website. Refer to Appendix A for instructions on how to complete the form. First persons are requested to complete one form per patent, per submission, per DIN.

4.2 Timing requirements

A first person wishing to file a patent list for a particular drug must meet the timing requirements set out in subsections 4(5) and 4(6) of the PM(NOC) Regulations. The timing requirements continue to apply during the reconsideration process set out in Health Canada's Guidance Document Reconsideration of Decisions Issued for Human Drug Submissions.

4.2.1 Patent Lists at time of filing a submission

Pursuant to subsection 4(5) of the PM(NOC) Regulations, a first person wishing to submit a patent list must do so at the time it files the new drug submission or supplement to a new drug submission to which the patent list relates. Only patent lists that accompany the drug submission will be accepted and patent lists submitted separately will be refused as not meeting the timing requirements.

4.2.2 Patent Lists after time of filing a submission

Pursuant to subsection 4(6) of the PM(NOC) Regulations, a first person may also submit a patent list in respect of a previously filed drug submission provided that the following conditions are met:

a) the Canadian filing date of the patent precedes the drug submission filing date, and

b) the patent list is submitted to the TPD within thirty days after the issuance of the patent.

In these circumstances, a first person must, in addition to submitting all of the information required under subsection 4(4), identify the submission number to which the newly granted patent relates.

4.3 Content requirements and prioritisation

All patent lists received by the TPD will be evaluated for completeness against the list of required information set out in subsection 4(4) of the PM(NOC) Regulations. It should be noted, however, that the TPD does not have a duty to make corrections or suggestions or inform first persons of any deficiencies in the content of patent lists.

In the case of a newly-issued patent, it is recommended that patent lists be submitted to the TPD as soon as possible. Where deficiencies are identified, first persons may have an opportunity to correct a patent list or submit additional patent lists before the end of the 30-day period. For more information on how to complete a Form IV Patent List, please consult Appendix A.

In order to expedite the evaluation by the TPD, first persons are encouraged to include (i.e. as part of the cover letter) with their patent lists a list of eligible patent claims and a description of how such claims correspond to the drug submission in respect of which the patent list is filed, as well as page references to relevant portions of the drug submission, where applicable. The TPD will prioritise evaluations for submissions for which an NOC has already issued.

4.4 Drug submissions eligible for filing a Patent List

In accordance with subsection 4(1) of the PM(NOC) Regulations, a patent list may be filed in relation to a new drug submission or a supplement to a new drug submission. Both "new drug submission" and "supplement to a new drug submission" are defined in subsection 3(1) of the PM(NOC) Regulations. Pursuant to these definitions and to subsections 4(2) and 4(3), only the following clearly defined submission types provide an opportunity to add a patent to the Patent Register:

- a new drug submission, except a new drug submission based solely on the change of name of the manufacturer (see definition of "new drug submission" in subsection 3(1))
- a supplement to a new drug submission for a change in formulation
- a supplement to a new drug submission for a change in dosage form
- a supplement to a new drug submission for a change in use of the medicinal ingredient

4.5 Product specificity requirements

In addition to the timing, content and submission requirements outlined in the previous sections, section 4 of the PM(NOC) Regulations sets out additional product-specificity requirements which are to be considered in determining the eligibility of a patent to be added to the Patent Register.

As discussed in the RIAS accompanying the October 5, 2006 amendments, in order for a patent to qualify for protection under the PM(NOC) Regulations, it must be relevant to the drug product the first person is approved to sell. The amendments entrench the concept of drug product specificity as the key consideration required of the Minister in applying the eligibility requirements under the PM(NOC) Regulations. In turn, the amended language more precisely reflects the intended link between the subject matter of a patent on a patent list and the content of the underlying submission for the NOC in relation to which it is submitted.

4.5.1. Patent List in relation to a New Drug Submission

In order to be eligible to be added to the Patent Register, the patent must contain a claim for the medicinal ingredient, a claim for the formulation containing the medicinal ingredient, a claim for the dosage form, or a claim for the use of the medicinal ingredient, which has been approved through the issuance of a NOC in respect of the submission.

The TPD considers the following three questions when applying the requirements of section 4 of the PM(NOC) Regulations.

1. What does the patent claim?
2. What is approved in the submission?
3. Does the patent claim what is approved in the submission?

In general, the TPD will not consider the following types of patents as being eligible to be added to the Patent Register:

- a purely process patent
- a patent for a medical device
- a patent for an intermediate used in the manufacture of the medicinal ingredient
- a patent for a metabolite of the medicinal ingredient, and
- a patent for an impurity present in the final drug product

Claim for the medicinal ingredient

As specified in the definition of "claim for the medicinal ingredient", product-by-process patents and patents claiming biological drugs are eligible to be added to the Patent Register provided that all other requirements set out in the PM(NOC) Regulations are met. This definition also clarifies that patents claiming different polymorphs of the medicinal ingredient are eligible for listing. As specified in the RIAS accompanying the October 5, 2006 amendments to the PM(NOC) Regulations, the term "polymorph" is meant to include different crystalline, amorphous, hydrated and solvated forms of the approved medicinal ingredient.

A patent claiming an enantiomer is not eligible to be added to the Patent Register in respect of a medicinal ingredient that is a racemate. In addition, a patent that claims varying ratios of enantiomers is not eligible to be added to the Patent Register with respect to a racemate of the medicinal ingredient. Similarly, a patent directed specifically to a racemic mixture or a mixture of two enantiomers in varying ratios will not be eligible to be added to the Patent Register in relation to a drug containing only one of the enantiomers.

In accordance with subsection 4(2.1), a patent that claims a medicinal ingredient is eligible to be added to the Patent Register in respect of a drug that contains that medicinal ingredient in combination with other medicinal ingredients. However, patents claiming a combination of medicinal ingredients contained in a single formulation or dosage form are not eligible to be added to the Patent Register in respect of a drug that contains only one of the claimed medicinal ingredients.

Claim for the formulation that contains the medicinal ingredient

The formulation claimed in the patent must correspond to the formulation approved in the relevant drug submission. A claim for the formulation may or may not specify non-medicinal ingredients.

Under paragraph 4(2.1)(b), a patent that contains a claim for the formulation is eligible to be added to the Patent Register if the drug contains the non-medicinal ingredients in the claim, even if the drug contains additional non-medicinal ingredients.

For example, a patent claiming a formulation that contains non-medicinal ingredient X would not be eligible to be added to the Patent Register in respect of a drug that does not contain non-medicinal ingredient X. Conversely, the same patent would be eligible to be added to the Patent Register in respect of a drug that contains non-medicinal ingredients X and Y.

Claim for the dosage form

The dosage form claimed in the patent must correspond to the dosage form approved in the relevant drug submission as noted on the NOC. This would include novel dosage forms, for example, patents that claim:

- a patch
- an extended-release tablet or capsule, and
- an implant

However, patents directed solely towards a dispenser, a container or packaging (e.g. an inhaler, an intravenous stand, or a syringe) would not be considered to contain a claim for the dosage form.

Claim for the use of the medicinal ingredient

The TPD will refer to the indication section of the Product Monograph (PM) of the drug to determine whether or not the patent claims an approved use of the medicinal ingredient. However, it is not expected that the language in the patent will be reproduced exactly in the PM. As PMs do not exist for veterinary products, generally the labelling information and package insert will be used.

A patent containing a claim for the use of a medicinal ingredient is eligible to be added to the Patent Register in respect of a drug that contains that medicinal ingredient in combination with other medicinal ingredients, if the drug is approved for the use claimed in the patent. Patents claiming the use of a combination of medicinal ingredients will generally not be eligible to be added to the Patent Register against a drug containing only one of the medicinal ingredients in the combination. However, patents claiming the use of a medicinal ingredient in combination with one or more other medicinal ingredient(s) are eligible to be added to the Patent Register, if said combination use is found in the indication section of the drug's approved PM. However, in order to be eligible, the patent claims must not be limited to the use of the combination in a single formulation or dosage form.

For example, a patent claiming the sequential use of medicinal ingredient A in combination with medicinal ingredient B for the treatment of X could be added to the Patent Register in respect of a drug solely containing medicinal ingredient A, if the claimed use of the combination is found in the drug's approved PM.

4.5.2 Patent List in relation to a Supplement to a New Drug Submission

A new patent may only be added to the Patent Register in respect of the following three specific types of supplements to a new drug submission:

- a supplement to a new drug submission for a change in formulation (this includes a change in strength)
- a supplement to a new drug submission for a change in dosage form, and
- a supplement to a new drug submission for a change in use of the medicinal ingredient

In addition to this requirement and in keeping with the product-specificity requirements, the patent will only be eligible to be added to the Patent Register if it contains a claim for the very change approved in the supplement. Therefore, if the supplement is for a new formulation, dosage form or use, the patent must

contain a claim for the new formulation, dosage form or use in order to be eligible to be added to the Patent Register. Subsection 4(3) of the PM(NOC) Regulations does not allow the addition of patents containing claims solely for the medicinal ingredient (including polymorphic forms).

The TPD considers the following three questions when applying the requirements of subsection 4(3) of the PM(NOC) Regulations.

1. What does the patent claim?
2. What is the change approved in the submission?
3. Does the patent claim the very change approved in the submission?

4.5.3 Carry-forward provision

Subsection 4.1(2) of the PM(NOC) Regulations is a "carry-forward" provision. Under subsection 4.1(2), a first person who submits a patent list in relation to a new drug submission referred to in subsection 4(2) may, if the list is added to the register, resubmit the same list in relation to a supplement to the new drug submission, but may not submit a new patent list in relation to a supplement except in accordance with subsection 4(3). Similarly, a patent on a patent list that has been added to the Patent Register in respect of a supplement under subsection 4(3) may be "carried forward" in respect of a subsequently approved supplement.

The TPD is required to give effect to the product-specificity requirements in applying the "carry-forward" provision under subsection 4.1(2). As such, patents which are already included on the Patent Register will be "carried forward" to a new DIN, provided the product-specificity requirements continue to be met (e.g. a patent that contains a claim for the medicinal ingredient will be carried forward in respect of a supplement for a new strength or dosage form).

In all cases, the TPD will apply the same timing requirements to patent lists submitted under the "carry-forward" provision as are applied to patent lists submitted under section 4 of the PM(NOC) Regulations. When submitting a patent list with a supplement and the patent is already included on the Patent Register, the TPD recommends that the first person submit such a patent list under the "carry forward" provision, unless the patent contains a specific claim for the changed formulation, the changed dosage form or the changed use, for which the supplement was submitted.

4.5.4 Consultation

As permitted by subsection 3(8) of the PM(NOC) Regulations, the TPD may consult with officers or employees of the Patent Office in the Canadian Intellectual Property Office (CIPO) regarding the claims construction of the patent. CIPO may be consulted to verify if a patent has lapsed. The TPD may also consult with the relevant review area within the HPFB, where necessary, regarding the information in the drug submission (e.g. regarding the approved use of the medicinal ingredient).

4.6 Process

For patent lists submitted at the time of filing of a drug submission and for newly-issued patents submitted for drug submissions under review, the TPD will conduct a preliminary evaluation to ensure that the patents meet all eligibility requirements. If a patent is preliminarily found to be eligible, the TPD will inform the first person in writing, indicating that the eligibility determination is subject to a final review at the time of issuance of the NOC. The TPD will conduct a final check of the eligibility of the patent prior to addition to the Patent Register, as what is approved may be different from what was initially submitted. This final check is to ensure that no significant changes were made to the drug submission during the review process that would affect the patent eligibility, for example, changes to the indication, dosage form, route of administration or strength of the drug. The final patent check will also ensure that there have been no changes to the jurisprudence which would affect the eligibility of the patent for addition to the Patent Register. This check does not delay the issuance of the NOC.

If the TPD preliminarily determines a patent to be ineligible, the TPD will notify the first person, in writing, that the patent has been found ineligible to be added to the Patent Register. The first person will then be provided with an opportunity to submit written representations as to the patent's eligibility to be added to the Patent Register. If representations are provided, they will be taken into consideration by the TPD and a final decision regarding the patent eligibility will subsequently be communicated to the first person.

4.7 Certificates of Supplementary Protection

A certificate of supplementary protection (CSP) provides an additional period of protection, of up to 2 years, for drugs containing a new medicinal ingredient, or a combination thereof, protected by an eligible patent. For more information on certificates of supplementary protection, please consult the Health Canada Guidance Document Certificate of Supplementary Protection Regulations.

In accordance with subsection 4(3.1) of the PM(NOC) Regulations, a CSP is eligible to be added to the Patent Register in respect of a new drug submission or supplement if two requirements are met. The first requirement is that the patent set out in the CSP must be included on the Patent Register in respect of that submission or supplement. The second requirement is that the submission or supplement relates to a drug with respect to which the CSP grants rights, privileges and liberties referred to in section 115 of the Patent Act.

Section 115 of the Patent Act provides that the scope of the CSP is the same as that of the patent, but only with respect to the making, constructing, using or selling of any drug that contains the medicinal ingredient or combination of medicinal ingredients set out in the certificate, by itself or in addition to any other medicinal ingredient.

The following scenarios are provided as examples.

Example 1a:

CSP No. 1 is issued in relation to medicinal ingredient X and the new drug submission for Drug A. The patent set out in CSP No. 1 is included on the Patent Register in respect of Drug A. The scope of the CSP includes Drug A because Drug A contains medicinal ingredient X. As both requirements of subsection 4(3.1) are met, CSP No. 1 is eligible to be added to the Patent Register in respect of Drug A.

Example 1b:

The patent set out in CSP No. 1 is included on the Patent Register in respect of Drug B. Drug B contains medicinal ingredient X in combination with medicinal ingredient Y. The scope of CSP No. 1 includes Drug B because Drug B contains medicinal ingredient X. As both requirements of subsection 4(3.1) are met, CSP No. 1 is eligible to be added to the Patent Register in respect of Drug B.

Example 2:

CSP No. 2 is issued in relation to medicinal ingredient W and the new drug submission for Drug C. However, the patent set out in CSP No. 2 is not included on the Patent Register in respect of Drug C. Therefore, the requirement of paragraph 4(3.1)(a) is not met and CSP No. 2 is not eligible to be added to the Patent Register.

Example 3:

CSP No. 3 is issued in relation to the new drug submission for Drug D, containing medicinal ingredient Y.

The patent set out in CSP No. 3 is included on the Patent Register in respect of Drug D, containing medicinal ingredient Y. Drug D is within the scope of CSP No. 3 because it contains the medicinal ingredient set out in the CSP. Therefore, CSP No. 3 is eligible to be added to the Patent Register in respect of Drug D.

The patent set out in CSP No. 3 is also included on the Patent Register in respect of another drug, Drug E, containing medicinal ingredient Z. CSP No. 3 does not grant rights, privileges and liberties in respect of Drug E in accordance with section 115 of the Patent Act, as Drug E does not contain the medicinal ingredient Y or the

"same" medicinal ingredient, per the Certificate of Supplementary Protection Regulations and section 105 of the Patent Act. Therefore, CSP No. 3 is not eligible to be added to the Patent Register in respect of Drug E because the requirement of paragraph 4(3.1)(b) of the PM(NOC) Regulations is not met.

4.7.1 Process

Once issued, all CSPs will be assessed by the TPD in accordance with subsection 4(3.1) of the PM(NOC) Regulations for eligibility to be added to the Patent Register without requiring a separate form or request from the first person. To assess the eligibility of a CSP, the TPD will first determine if the patent set out in the CSP is included on the Patent Register. If the patent is included on the Patent Register, the TPD will assess whether the drug on the Patent Register is a drug with respect to which the CSP grants rights, privileges and liberties referred to in section 115 of the Patent Act. If the patent is not on the Patent Register, the CSP is not eligible to be added to the Patent Register, and the TPD will not provide an assessment in writing.

For CSPs found eligible for addition to the Patent Register, the TPD will insert the CSP number and expiry date in the office use section of the corresponding patent list(s) and will update the Patent Register. The first person will also be notified in writing. The expiry date of the CSP will be reflected in a separate field on the Patent Register from the expiry date of the patent.

If the patent set out in the CSP is included on the Patent Register, but the TPD determines that the CSP is not eligible to be added to the Patent Register, the first person will be notified in writing. The first person will have the opportunity to provide representations. The TPD will consider any representations before a final decision is made.

It is possible that a CSP will be added to the Patent Register before publication of the CSP issuance on the Register of Certificates of Supplementary Protection and Applications.

When completing a Form IV patent list for a patent that is set out in a CSP, first persons should provide the information relating to the patent only. For example, enter the patent number and the expiry date of the patent in Part 3 of the form, and not the CSP number or expiry date. The TPD will insert the information in relation to the CSP in the office use section of the form. In accordance with subsection 4(1.1) of the PM(NOC) Regulations, a patent list may include a patent that has expired if it is set out in a CSP that has taken effect. As such, if a patent has expired and the term of a CSP is in effect when submitting a Form IV patent list with a submission, the first person should continue to enter the patent information on the form, as described above.

4.8 Addition of patent(s) and CSP(s) to the Patent Register

As provided for in subsection 3(7) of the PM(NOC) Regulations, no patent on a patent list or CSP shall be added to the Patent Register until the drug submission in respect of which the patent list was submitted receives an NOC. In addition to this requirement, the TPD will not add any patent or CSP until it has completed a final evaluation and is satisfied that the patent or CSP meets the eligibility requirements set out in section 4, described above. The TPD will prioritise evaluations for submissions for which an NOC has already issued.

It is recognised that certain terminology proposed by the company at the time of filing a drug submission does not become final until review and approval through the issuance of an NOC. Therefore, at the time of NOC issuance, it is possible that the information on Part 2 of the Form IV does not match the NOC, e.g. the medicinal ingredient, brand name, strength, route of administration and dosage form. If this information does not match the NOC, the first person is expected to request updates to the patent list, in accordance with the obligations set out in subsection 4(7). The TPD will not update a patent list without written permission from the first person. Replacement Form IVs should not be provided by first persons.

Upon receipt of the written permission, the TPD will make the requested changes to the Form IV to align the terminology on the Form IV with that approved on the NOC. Where permission is not received in a timely manner, there may be delays in adding the patent lists to the Patent Register.

4.9 Accuracy of Patent List information

Pursuant to subsection 4(7), first persons are required to keep the information on their patent lists up to date. The update of information, however, does not provide an opportunity to add a new patent. A first person should notify the TPD in writing of any updates to the information included on the patent lists. Examples of an update include a change to the company name or address, the name and address for service of a notice of allegation, patent lapse, or the dedication of the patent to the public interest. The onus is on the first person to ensure that the information on the patent list and the Patent Register is accurate and current. Please note that due to the complexities of corporate mergers and acquisitions, information is not automatically updated when an NOC is issued for a company name change or merger.

To ensure receipt of a notice of allegation from a second person, the company name and address for service must be current. First persons wishing to update a patent list should forward to the TPD a letter outlining the requested changes. First persons are requested not to provide the TPD with new forms. The TPD will not assume any responsibility for errors arising from the failure of the first person to provide up-to-date information. First persons are encouraged to view the Form IVs on the Patent Register, available online, to ensure the accuracy of the information.

4.10 Re-issued patents

If a patent that is included on the Patent Register is re-issued by CIPO, the TPD recommends that the first person submit a new Form IV patent list within 30 days of the date of re-issuance. The granted date entered on the patent list should be the date the patent was re-issued. The TPD will conduct a review to determine whether the patent remains eligible to be included on the Patent Register. If the TPD is of the view that the patent is no longer eligible, the TPD will notify the first person, in writing, that the patent has been found ineligible for inclusion on the Patent Register. The first person will then be provided with an opportunity to submit written representations as to the patent's eligibility for inclusion on the Patent Register. If representations are provided, they will be taken into consideration by the TPD and a final decision regarding the patent eligibility will subsequently be communicated to the first person.

5. Section 5 of the PM(NOC) Regulations

5.1 Scope and application of Section 5

In accordance with subsection 5(1), when a second person files a submission seeking an NOC for a drug and the submission directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada by a first person and in respect of which there are patents and/or CSPs included on the Patent Register, the second person must include in the submission the required statements or allegations set out in subsection 5(2.1) of the PM(NOC) Regulations.

Subsection 5(2) applies when a second person files a supplement for a change in formulation, a change in dosage form, or a change in use of the medicinal ingredient and the supplement directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada by a first person and in respect of which there are patents and/or CSPs included on the Patent Register.

While the terminology in section 5 is intended to capture abbreviated new drug submissions (ANDSs) and supplements to abbreviated new drug submissions (SANDSs), the language of section 5 of the PM(NOC) Regulations is not exclusive to ANDSs and SANDSs. It is also intended to capture new drug submissions (NDSs) that directly or indirectly compare the drug with, or make reference to, another drug marketed in Canada, including biosimilar drug submissions and submissions relying on third-party data.

A biosimilar must be subsequent to a biologic drug that is approved in Canada and to which a reference is made. Sponsors may use a non-Canadian sourced version as a proxy for the Canadian drug in the comparative studies. If the Canadian drug is marketed in Canada and has patents or CSPs included on the

Patent Register, new drug submissions and supplements submitted in accordance with Health Canada's Guidance Document: Information and Submission Requirements for Biosimilar Biologic Drugs are considered to make a comparison or reference within the meaning of section 5. Sponsors of such submissions will be required to comply with the requirements for second persons under the PM(NOC) Regulations.

NDSs which seek approval based on independent clinical trials and not on a comparison or reference to a drug which has patents and/or CSPs included on the Patent Register are not captured by section 5. In addition, submissions that do not result in a subsequent entry version of the drug which has patents and/or CSPs included on the Patent Register are not captured by this section. For example, a submission for a drug indicated for use in combination with a drug on the Patent Register will not be required to comply with section 5 of the PM(NOC) Regulations.

5.1.1 Administrative drug submissions

When a manufacturer files a drug submission in accordance with Health Canada's Guidance Document Administrative Processing of Submissions and Applications: Human or Disinfectant Drugs, the administrative drug submission does not trigger application of section 5 of the PM(NOC) Regulations.

Rather, only the originating NDS or originating ANDS which directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada under an NOC issued to a first person, will trigger the application of section 5 of the PM(NOC) Regulations.

Subsequently filed administrative drug submissions that cross-reference the originating drug submission will not re-trigger section 5 of the PM(NOC) Regulations and should not include a Form V: Declaration Re: Patent List ("Form V"). An NOC will be issuable in respect of an administrative drug submission after the requirements of the Food and Drug Regulations have been met and only after the originating drug submission receives its NOC. In the case where the originating drug submission is placed on intellectual property hold, the administrative drug submission will also be placed on intellectual property hold.

If consent is received from the patent owner under subsection 7(2) of the PM(NOC) Regulations, or subsection 7(3) of the pre-September 21, 2017 version of the PM(NOC) Regulations, and the NOC issues for the originating drug submission, the NOC for the administrative drug submission will also issue, as the requirements of the PM(NOC) Regulations have been met for the originating drug submission.

In accordance with subsection 5(4) of the PM(NOC) Regulations, the date of filing on which the Patent Register is frozen is specific to the originating drug submission. As such, any patent added to the Patent Register in respect of the first person's drug on or after the date of filing of the originating drug submission need not be addressed in respect of the administrative submission. The Patent Register is, in effect, "frozen" as of the date of filing of the originating drug submission.

Example 1:

Generic A files an ANDS for its drug X on January 2, 2018 and addresses the patents included on the Patent Register in respect of the first person's drug prior to January 2, 2018 as required by section 5 of the PM(NOC) Regulations. Subsequently, Generic A receives an NOC for its drug X.

Generic B then enters into a licensing agreement with Generic A and files an administrative ANDS for its identical drug XX, cross-referencing Generic A's ANDS. Generic A continues marketing its drug X while Generic B is assigned a distinct DIN for its drug XX after the requirements of the Food and Drug Regulations have been met.

Subsection 5(1) of the PM(NOC) Regulations is not re-triggered in respect of Generic B's administrative ANDS for its drug XX. Therefore, Generic B does not need to address the patents included on the Patent Register in respect of the first person's drug prior to receiving an NOC for its drug XX.

Example 2:

Generic C files an ANDS for its drug Y on January 2, 2018 and elects to await expiry of the patents included on the Patent Register in respect of the first person's drug prior to January 2, 2018. Subsequently, upon meeting the requirements under the Food and Drug Regulations, Generic C's ANDS for its drug Y is placed on intellectual property hold.

Generic D then enters into a licensing agreement with Generic C and files an administrative ANDS for its identical drug YY, cross-referencing Generic C's ANDS.

An NOC is issuable in respect of Generic D's administrative ANDS for its drug YY after the requirements of the Food and Drug Regulations have been met and only after Generic C receives an NOC for its ANDS for its drug Y. Therefore, Generic D's administrative ANDS will be placed on intellectual property hold until the NOC issues for Generic C's drug.

5.2 Submission of a Form V: Declaration re: Patent List

Under subsections 5(1) and 5(2) of the PM(NOC) Regulations, a second person must include in the submission or supplement the required statements or allegations set out in subsection 5(2.1) for each patent and CSP included on the Patent Register in respect of the first person's drug. The required statements and allegations are set out in the Form V. One Form V must be submitted for each patent included on the Patent Register, and for each strength of the second person's drug. Refer to Appendix B for instructions on how to complete the Form V.

Every required Form V must be a part of a drug submission. Filing of a Form V prior to the filing of a drug submission or supplement to a drug submission is not permitted. However, revised Form Vs are accepted by the TPD.

A submission or supplement requiring a Form V will be considered administratively incomplete without one. It will be placed on "Patent-Form V" hold and will not be transmitted to the relevant reviewing bureau/centre until the required Form V has been received by the TPD. The filing date of the submission is as defined above in section 2 of this document.

A second person will be required to address all patents that are added to the Patent Register before the date of filing of its submission or supplement. If a second person cancels its submission or supplement and subsequently re-files, or the relevant directorate issues a rejection letter (e.g. a screening rejection letter, a notice of non-compliance-withdrawal or a notice of deficiency-withdrawal), the original date of filing is lost and the new date of filing becomes the date on which the submission or supplement is re-filed and considered administratively complete.

5.3 Freezing the Patent Register: addressing additions to the Patent Register on or after the date of filing of a second person's submission or supplement

Under subsection 5(4) of the PM(NOC) Regulations, a second person is not required to address a patent, or associated CSP setting out that patent, added to the Patent Register in respect of the first person's drug on or after the date of filing of the second person's submission. The Patent Register is, in effect, "frozen" in respect of the patents included on the register as of the date of filing of the second person's submission.

The date of filing on which the Patent Register is frozen is specific to a second person's submission or supplement. Each second person benefits from the same freezing mechanism as of the date of filing of their respective submissions or supplements with the HPFB.

The PM(NOC) Regulations address the possible situation where a CSP is added to the Patent Register after the second person has filed its submission or supplement, but where the patent set out in the CSP was added to the Patent Register before the second person filed its submission or supplement. If this occurs, the PM(NOC) Regulations prohibit the issuance of an NOC to the second person until the expiry of the CSP, if certain conditions are met. The CSP must set out a patent in respect of which the second person was

required to make a statement or allegation but did not make an allegation, or a patent in respect of which the Court has made a declaration of infringement. In addition, the CSP must be included on the Patent Register in respect of the same submission or supplement as the patent.

5.4 Certification of date of filing

When a second person's submission or supplement is considered administratively complete, the TPD will issue to the second person an acknowledgement and certification letter to certify the date of filing of the submission. This letter will be identified by the title "Acknowledgement and Certification of Information Received".

Under subparagraph 5(3)(c)(i) of the PM(NOC) Regulations, this certification must be served with a notice of allegation on the first person. Please note that the acknowledgement and certification is not the same as a regular acknowledgement letter, which does not have the title "Acknowledgement and Certification of Information Received". The acknowledgement letter does not certify the date of filing of the submission.

5.5 Deemed date of filing under Canada's Access to Medicines Regime

In cases where a second person has filed a submission or supplement under Canada's Access to Medicines Regime (CAMR), also known as An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa), subsection 5(5) of the PM(NOC) Regulations provides for a deemed date of filing in order to comply with the data protection provisions under section C.08.004.1 of the Food and Drug Regulations.

CAMR provides a framework within which eligible countries can import less expensive generic versions of patented drugs and medical devices. Notwithstanding that a second person may receive authorization to export a given drug under a compulsory license granted by the Commissioner of Patents, the HPFB will not grant an NOC providing Canadian market authorization unless the requirements for both data protection under section C.08.004.1 of the Food and Drug Regulations, and the PM(NOC) Regulations have been met.

Subsection C.08.004.1 of the Food and Drug Regulations provides an eight-year period of market exclusivity for innovative drugs. In addition, a subsequent-entry manufacturer is prevented from filing a submission for a copy of that innovative drug for the first six years of the eight-year period. The eight-year period may be extended by six months through a pediatric extension. The introduction of the six-year no filing period requires an exception to allow for the filing of drug submissions within the framework of CAMR.

The addition of subsection 5(5) to the PM(NOC) Regulations provides this exception. For the purpose of subsection 5(3), which governs the service of a notice of allegation, and subsection 5(4), which governs the freezing of the Patent Register, there is a deemed date of filing for submissions and supplements filed under CAMR, and referred to in paragraph C.07.003(b) of the Food and Drug Regulations. That date of filing is deemed to be six years after the date of issuance of the first person's notice of compliance provided that:

1) the drug to which the second person makes a comparison or reference is an innovative drug within the meaning of subsection C.08.004.1(1) of the Food and Drug Regulations, and

2) the date that the submission or supplement is received by the HPFB is less than six years from the day on which the first NOC was issued in respect of the innovative drug.

The result is that, under section 5(3) of the PM(NOC) Regulations, a second person may not serve a notice of allegation before the deemed filing date of its submission or supplement, which is six years after the date of issuance of the first person's NOC.

In addition, under section 5(4), the Patent Register will be frozen six years after the date of issuance of the first person's NOC. Until that time, a first person may continue to add patents to the Patent Register in accordance with the PM(NOC) Regulations.

5.6 Notice of Allegation and information to be served on a First Person

5.6.1 Timing of service

Under paragraph 5(3)(a) of the PM(NOC) Regulations, a second person who makes an allegation under paragraph 5(2.1)(c) must serve on the first person a notice of allegation relating to the submission or supplement that forms the basis of the allegation, but may not do so before the filing date of the submission or supplement.

The address for service of the first person is located on the patent list. Service by registered mail (as defined by Canada Post) is deemed to be effected on the addressee five days after mailing.

5.6.2 Contents of Notice of Allegation and documents served with a Notice of Allegation

Under subparagraph 5(3)(b)(i) of the PM(NOC) Regulations, a notice of allegation (NOA) must include a description of the medicinal ingredient, dosage form, strength, route of administration and use of the drug in respect of which the submission or supplement has been filed. The TPD will verify that this information corresponds with that of the submission or supplement on file with the HPFB. The TPD will also verify that the manufacturer in the submission is the same as the second person who has served the NOA. If any piece of information is missing from the NOA, or does not correspond with the information in the submission or supplement, the TPD will notify the second person of the deficiencies identified in the NOA. As a transparency measure, the TPD will also copy the first person on this correspondence. The second person will be required to serve a notice of allegation reflecting all of the correct information outlined in subparagraph 5(3)(b)(i) of the PM(NOC) Regulations.

A certification of the date of filing of the submission or supplement is required to be served with the notice of allegation. As discussed above, the certification of the date of filing of the submission or supplement is provided by the TPD in the form of the "Acknowledgement and Certification of Information Received" letter.

5.6.3 Information to provide to the TPD

In accordance with paragraph 5(3)(e) of the PM(NOC) Regulations, the second person must provide to the TPD proof of service of the NOA, along with a copy of the NOA. A copy of the documents required to be served with the notice of allegation under paragraphs 5(3)(c) and 5(3)(d) do not need to be provided to the TPD.

It is recommended that second persons provide the proof of service and a copy of the NOA to the TPD as soon as possible following service on the first person to allow the TPD a period of time to review the NOA. Allowing for a period to review the NOA to ensure the information required by subparagraph 5(3)(b)(i) is included in the NOA and corresponds with the submission or supplement may provide an opportunity for second persons to address any deficiencies before an action is brought by the first person or patent owner.

5.6.4 Retraction of a Notice of Allegation

Under section 5(6), a second person who has served a notice of allegation on a first person must retract that notice of allegation and serve a notice of retraction on the first person within 90 days after either:

1) the date on which the Minister notifies the second person under paragraph C.08.004(3)(b) or C.08.004.01(3)(b) of the Food and Drug Regulations that the submission or supplement does not comply with the requirements of section C.08.002, C.08.002.01, C.08.002.1 or C.08.003, as the case may be, or section C.08.005.1, or

2) the date of the cancellation by the second person of the submission or supplement to which the allegation relates.

The types of notices requiring a retraction of a notice of allegation include, for example, a screening rejection letter, a notice of non-compliance-withdrawal or a notice of deficiency-withdrawal.

A copy of the retraction or withdrawal of the notice of allegation should be provided to the TPD. The TPD will acknowledge the retraction or withdrawal in writing, and will copy the first and second person.

5.7 Second Person company name changes prior to NOC issuance

A second person's submission may be transferred to another manufacturer prior to NOC issuance, if there is a company merger or licensing agreement. If an NOA has been served on the first person, the new second person should notify the first person of its new name in order to ensure transparency.

6. Sections 6 and 7 of the PM(NOC) Regulations

6.1 Actions

When a first person is served with a notice of allegation, the first person or patent owner may bring an action against the second person in the Federal Court for a declaration that the making, constructing, using or selling of the second person's drug would infringe any patent or CSP that is the subject of an allegation. The first person or patent owner has a period of 45 days after the date of service of the notice of allegation to bring the action. If an action is brought, the Minister is prohibited from issuing the NOC to the second person for up to 24 months (the statutory stay).

6.2 Intellectual property hold

Once the examination of a second person's submission has been completed, the submission will be placed on "Intellectual Property (IP) Hold" if the requirements of the PM(NOC) Regulations have not been met. The manufacturer will be notified in writing of the date on which the examination was completed and that the submission has been placed on hold. An invoice for the review of the submission will also be issued. Once the requirements of the PM(NOC) Regulations have been met, the submission may remain on "IP Hold" until the expiration of any data protection period for the first person's drug under section C.08.004.1 of the Food and Drug Regulations.

Where there is a notifiable change submission, it will be placed on IP Hold while the related submission is on IP Hold. The manufacturer will not be notified in writing when a notifiable change submission has been placed on hold. Second persons are encouraged to view the status of their submissions in the Drug Submission Tracking System - Industry Access. The status of the notifiable change submission will be updated to "IP Hold" when the review of the submission is complete.

In accordance with subsection 8(2) of the amended PM(NOC) Regulations and paragraph 8(1)(a) of the pre-September 21, 2017 version of the PM(NOC) Regulations, the Minister may be requested to certify the date on which a notice of compliance would have been issued to a second person in the absence of the PM(NOC) Regulations.

6.3 NOC issuance to a Second Person in the absence of an action for patent infringement

A first person or patent owner has a period of 45 days following service of a notice of allegation to bring an action in the Federal Court. If no action is brought, the NOC may be issuable to the second person on the 46th day after the notice of allegation was served, if the requirements of the Food and Drug Regulations have been met. As such, the TPD will verify on day 46 whether a copy of a statement of claim has been received.

The Minister of Health is not a party to actions for patent infringement, therefore a copy of the statement of claim should not be served on the Minister. However, in accordance with section 6.13 of the PM(NOC) Regulations, a copy of the statement of claim must be provided to the TPD as soon as feasible. Please refer to section 3.4.1 of this document for information on how to provide the statement of claim to the TPD.

The TPD will rely on the absence of a statement of claim to establish that no action was brought in the Federal Court. It is recommended that first persons and patent owners provide a copy of the statement of claim to the TPD within the 45-day period to avoid any unwanted issuance of an NOC to the second person.

6.4 Verification of portions of a submission or supplement

Pre-September 21, 2017 version of the PM(NOC) Regulations

Under paragraph 6(7)(a) of the pre-September 21, 2017 PM(NOC) Regulations, a second person may be ordered by the court to produce any portion of the submission or supplement filed for an NOC that is relevant to the disposition of the issues in the prohibition proceeding. In addition, the court may order the production of any changes, as they are made, to the portion during that proceeding.

Under paragraph 6(7)(b), the TPD may be ordered to verify that any portions of the submission or supplement produced by the second person correspond fully to the information in the submission or supplement, usually within 30 days of receipt of the productions. In such cases, the second person should produce the relevant documents directly to the first person. The first person will then direct the documents to the attention of the TPD through counsel for the TPD.

September 21, 2017 version of the PM(NOC) Regulations

Section 6.05 of the amended PM(NOC) Regulations provides that, on the request of any party to an action under the regulations, the TPD must verify that any portion of a submission or supplement that is required to be served with a notice of allegation, or that is produced as a result of an order, corresponds to the information in the submission or supplement. The documents to be verified shall be provided directly to the TPD as outlined in section 3.4.1 of this guidance document. To ensure a transparent process, the TPD recommends that the documents to be verified be provided by the first person or patent owner. Where the documents are provided by the second person, the TPD will not produce a copy to the first person or patent owner.

6.4.1 Verification process

The TPD is required only to verify whether the portions produced by the second person correspond with the relevant submission or supplement on file at the HPFB. The TPD is not required to produce additional documentation, or make any statements or characterizations regarding the nature of the portions produced by the second person. In keeping with the pre-September 21, 2017 practice, the TPD will endeavour to complete verification requests within 30 days.

To facilitate the verification process, parties are encouraged to continue to provide good quality copies of documents that are indexed using the format found in the example below, with respect to their location within the original submission or supplement.

If the productions are not formatted in a format acceptable to the TPD, they may be rejected for verification. To this effect, productions to be verified under either version of the PM(NOC) Regulations should be formatted as follows:

Index:

The documents should be indexed and tabbed. The index should denote the location of the documents from within the production. It is important to note that providing detailed descriptions and information in the index will assist the TPD in locating the documents and verifying the production efficiently.

Description of Item:

If multiple versions of a document were filed in respect of the relevant submission, for example a product monograph, add the "date of preparation" to the description (see Tab 2 of the example in Appendix C).

If multiple documents have similar titles, use a distinguishing name and/or highlight the difference(s) between the documents (see Tab 6 of the example in Appendix C).

Location:
If a document is located in a Master File, provide the Master File number and note whether the document can be found in the Unrestricted/Open or Restricted/Closed portion of the file (see Tabs 4 and 5 of the example in Appendix C).

Pages within a tab:
When only certain pages are provided for verification from a larger document, note the page numbers to be verified in the index and the complete number of pages of the document (see Tab 3 of the example in Appendix C).

Tabs:
Use a naming convention similar to "Tab 3 - [name of document]" when formatting the electronic production. If there are multiple documents contained in one tab, use one New Folder per tab (see Tab 7 of the example in Appendix C).

6.5 Consent

Under subsection 7(2) of the amended PM(NOC) Regulations, or subsection 7(3) of the pre-September 21, 2017 version of the PM(NOC) Regulations, the owner of the patent may provide consent to the making, constructing, using or selling of the drug in Canada by the second person.

The consent letter must be signed by the owner of the patent or by a person authorized to act on the owner's behalf. If the letter is signed by a person authorized to act on behalf of the patent owner, this must be stated in the letter. The letter should indicate the following:

- the patent and/or CSP numbers for which consent is being provided
- the second person's submission number
- the medicinal ingredient
- the second person's name, and
- a statement that for the purposes of subsection 7(2) or 7(3) of the PM(NOC) Regulations, as the case may be, the owner of the patent consents to the making, constructing, using or selling of the drug in Canada by the second person.

6.6 Renouncing the 24-month stay

Subsection 7(1)(d) of the amended PM(NOC) Regulations prohibits the Minister from issuing an NOC to a second person for a 24-month period from the day on which an action is brought under subsection 6(1). However, a party who brings an action may renounce application of this 24-month period under paragraph 7(5)(b). To do so, each of the parties who bring an action must provide to the TPD a notice that they renounce the application of the 24-month stay, at the time the action is brought.

The notice should indicate the following:

- the second person's submission number
- the patent and/or CSP numbers
- the court file number, and
- a statement that the application of paragraph 7(1)(d) of the PM(NOC) Regulations is being renounced in accordance with paragraph 7(5)(b) of the PM(NOC) Regulations.

7. Maintenance of the Patent Register

The TPD is responsible for maintaining the Patent Register in accordance with subsection 3(2) of the PM(NOC) Regulations. The TPD is required to add any patent on a patent list or CSP that meets the requirements for addition to the Register and to refuse to add any patent or CSP that does not meet the requirements for addition to the Register.

The TPD must also delete any patents or CSPs from the Patent Register as outlined in the PM(NOC) Regulations, as follows:

- if the patent or CSP was added to the Patent Register due to an administrative error
- if the patent or CSP has been declared invalid or void under subsection 60(1) or 125(1) of the Patent Act
- if the patent or CSP has been declared under subsection 6.07(1) to be ineligible for inclusion on the Register
- if the first person requests that the patent or CSP be deleted from the Patent Register
- if the patent has expired, unless a CSP in which that patent is set out is included on the Patent Register in respect of the same submission, or
- if the CSP has expired.

A patent or CSP declared ineligible for inclusion on the Patent Register will not be deleted until the period for appealing the decision to the Federal Court of Appeal ends, or until the conclusion of any appeal to the Federal Court of Appeal. This same delay does not apply to patents or CSPs declared invalid or void, which will be deleted after an initial finding. If a patent or CSP was deleted because of a finding of invalidity or ineligibility, it will be added back to the Patent Register, with a new date added, if the decision is subsequently reversed or set aside on appeal. Second persons who file submissions in the interim when the patent is not on the Patent Register will not need to address the patent. The first person will be notified in writing once a patent or CSP has been deleted from the Patent Register in accordance with paragraph 3(2)(c).

Subsection 3(2.3) provides the TPD with discretion to review the eligibility of all the patents on the Patent Register. This may occur when, for instance, the eligibility requirements are called into question by new jurisprudence. If it is necessary to undertake a review of the Patent Register under subsection 3(2.3) of the PM(NOC) Regulations, the TPD will notify first persons in writing if a patent or CSP has been found not to meet the requirements for inclusion on the Patent Register. If, during the course of such a review, an inquiry is received from an interested party regarding the inclusion of the patent on the Patent Register, a copy of the inquiry will be provided to the first person. As such, inquiries should not be marked confidential. The first person will then be provided with an opportunity to submit written representations as to the patent or CSP's eligibility for inclusion on the Patent Register. If representations are provided, they will be taken into consideration by the TPD and a final decision regarding the patent eligibility will subsequently be communicated to the first person and the inquirer. Note, however, that the mere receipt of an inquiry will not be considered as a sufficient basis to trigger a review of the entire Patent Register.

Appendices

Appendix A - How to complete a Form IV: Patent List

Please submit one Form IV per patent, per submission, per DIN.

Part 1

Select whether the patent list is being filed with the submission, or whether it is a newly issued patent for listing against a previously filed submission. The PM(NOC) Regulations require that all patents submitted for listing must be linked with a submission for an NOC. Therefore, in the case of a newly issued patent, the first person must provide the submission number. However, if the Form IV is being filed with the submission, the TPD will insert the submission number on the form.

Select "NDS" if the Form IV is to be added to the Patent Register in accordance with subsection 4(2) of the PM(NOC) Regulations. Select "SNDS" if the Form IV is to be added to the Patent Register in accordance with subsection 4(3) of the PM(NOC) Regulations, and then select the appropriate option(s): change in formulation, change in dosage form or change in use.

Select "Carry forward, in accordance with section 4.1(2)" if the patent is already included on the Patent Register and the patent is being resubmitted in relation to the submission or supplement.

Note: When submitting a patent list with an SNDS for a change in formulation, change in dosage form or change in use of the medicinal ingredient, and the patent is already listed on the Patent Register for the same product, the TPD recommends that the first person submit such a patent under the "carry forward" provision, unless the patent contains a specific claim for the changed formulation, dosage form or use for which the supplement was submitted.

Part 2

Enter the information about the drug as it appears, or as it is expected to appear, on the NOC.

Medicinal ingredient(s):

Enter the medicinal ingredient(s) contained in the drug as it appears, or as it is expected to appear, on the NOC.

Brand Name:

Enter the brand name under which the drug is (or will be) marketed. If the brand name has not yet been determined, it may be left blank and will be entered by the TPD when the NOC is issued.

Human or Veterinary:

Indicate human or veterinary.

Strength per unit:

Provide the strength of the medicinal ingredient(s) (e.g. 10 mg, 100 mg, 0.5 mg/10 ml). Please note that one Form IV should be submitted per DIN. If there is more than one medicinal ingredient, list the strengths in the order that the medicinal ingredients appear in the medicinal ingredient field. Therefore, the names of the medicinal ingredients do not need to be repeated in the strength field.

Dosage Form:

Provide the physical form of the drug (e.g. tablet, capsule, solution, powder) as it appears, or as it is expected to appear, on the NOC.

Route(s) of Administration:

Provide the route of administration of the drug (e.g. oral, nasal, subcutaneous) as it appears, or as it is expected to appear, on the NOC.

DIN:

In the case of the first submission for an NOC for a drug, the DIN will not be known by the first person. Therefore, this field should be left blank and the TPD will insert the DIN once the NOC issues. In all other cases, the DIN for the drug should be provided. Please note that one Form IV per DIN should be submitted.

Use(s) of the Medicinal Ingredient(s):

Enter the specific use(s) of the drug for which approval is being sought, or which has been approved, in the submission or supplement to which the patent list relates.

Part 3

Enter the information about the patent.

Patent Number:

Enter the Canadian Patent number being submitted for addition to the Patent Register. If a CSP has issued in respect of the patent, enter the patent number only in this section. The TPD will insert the CSP number and expiry date in the office use section, where applicable.

Code:

Indicate whether the first person is the owner of the patent, has an exclusive licence or has obtained consent from the owner of the patent to have it included on the patent list.

A: Applicant is the owner of the patent

B: Applicant has an exclusive license

C: Applicant has obtained the consent of the owner of the patent for the inclusion of the patent on the above patent list

Filing Date of Patent Application:

Indicate the Canadian patent application filing date.

Date Granted:

Enter the date on which the patent was granted by the Canadian Intellectual Property Office.

Expiration Date:

Enter the date on which the patent term will expire. The term of a patent is 20 years from date of filing for patent applications filed on or after October 1, 1989. For patent applications filed before October 1, 1989, the expiry date is the later of 17 years from date of grant of the patent or 20 years from the date of filing. If a CSP has issued in respect of the patent, enter the expiration date of the patent in this section. The TPD will insert the CSP number and expiry date in the office use section, where applicable.

Part 4

Enter the address in Canada for service, on the first person, of a notice of allegation referred to in paragraph 5(3)(a) or the name and address for service in Canada of another person on whom service may be made with the same effect as if service were made on the first person. A post office box (P.O.) box is not an acceptable address, as it cannot accept registered mail.

The TPD recommends using contact person titles (e.g. Director, Regulatory Affairs) rather than a name in this section to reduce the number of changes required to the form due to corporate staffing changes.

The onus is on the first person to keep this information up-to-date, in accordance with subsection 4(7) of the PM(NOC) Regulations.

Part 5

Enter the manufacturer and contact information and provide a certification that the information included on the patent list is accurate and that the patent on the list meets the eligibility requirements of subsection 4(2) or 4(3) of the PM(NOC) Regulations. The TPD will use the contact information provided in this section to correspond with the first person regarding the patent list.

Part 6

This section is for office use only.

Appendix B - How to complete a Form V: Declaration re Patent List

Please submit one Form V per patent, per submission, per DIN.

Part 1

Select whether the form is an amendment to a previously filed Form V, or if the Form V is being filed with the submission.

Part 2

Enter the information about the second person's drug.

Medicinal ingredient(s):

Enter the medicinal ingredient(s) contained in the second person's drug as it appears, or as it is expected to appear, on the NOC.

Brand Name:

Enter the brand name of the second person's drug as it appears, or as it is expected to appear, on the NOC.

Drug Use:

Indicate human or veterinary.

Strength per unit:

Provide the strength of the medicinal ingredient (e.g. 10 mg, 100 mg, 0.5 mg/10 ml). Please note that one Form V should be submitted per DIN. If there is more than one medicinal ingredient, list the strengths in the order that the medicinal ingredients appear in the medicinal ingredient field. Therefore, the names of the medicinal ingredients do not need to be repeated in the strength field.

Dosage Form:

Provide the physical form of the drug (e.g. tablet, capsule, solution, powder) as it appears, or as it is expected to appear, on the NOC.

Route(s) of Administration:

Provide the route of administration of the drug (e.g. oral, nasal, subcutaneous) as it appears, or as it is expected to appear, on the NOC.

Use(s) of medicinal ingredient(s):

Enter the specific uses of the drug for which approval is being sought in the second person's submission.

Part 3

Enter the information about the first person's drug.

Part 3.1

Provide the Canadian Patent Number and expiry date of each patent included on the Patent Register for the first person's drug. Please note that one Form V should be submitted per patent, per DIN.

If there is a Certificate of Supplementary Protection Number included on the Patent Register, enter the number and expiry date.

Part 3.2

In this section, the second person must select one of the statements or at least one of the allegations required by subsection 5(2.1) of the PM(NOC) Regulations.

Part 4

Provide the name and address of the manufacturer of the drug (the name of the company that is seeking the NOC) and contact information, which will be used by the TPD to correspond with the second person regarding the form. Any notice of allegation served should be from the company seeking the NOC.

Part 5

This section is for office use only.

Appendix C - Sample productions for verification

Sample Index Example

Tab	Sequence	Section	Description of Item	Location
1	0002	3.2.S.1.2	Quality - Body of Data - Drug Substance - Stability - Stability Data - Supplier Commitment	[Submission no.]
2	0005	1.3.1	Non-Annotated Product Monograph [date of preparation]	[Submission no.]
3	0004	3.2.S.3	Characterization, pp. 416-423 of 739	[Submission no.]
4	0000	1.0.4	Master File [Master File No.] - Administrative Information and Prescribing Information - Quality Overall Summary	Master File [Master File No.] - Open Portion or Closed Portion
5	The portions of [drug manufacturer name]'s Master File [Master File No.] that comprise the Productions are the following:			
	0001	3.2.S.1	General Information, pp. 6-7 of 739	Unrestricted Part or Restricted Part
6	0009	5.3.1.2	Comparative Bioavailability and Bioequivalence Study Reports: Comparative, Randomized 2-way Crossover Bioavailability Study of Tablets Under Fed Conditions, Drug Concentration by Formulation	[Submission no.]
			Comparative Bioavailability and Bioequivalence Study Reports: Comparative, Randomized 2-way Crossover Bioavailability Study of Tablets Under Fasting Conditions, Drug Concentration by Formulation	
7	0003	3.2.1.5	Drug Product - Specification(s) [drug name] - 10-mg-release-specifications	[Submission no.]
			Drug Product - Specification(s) [drug name] - 15-mg-release-specifications	[Submission no.]
			Drug Product - Specification(s) [drug name] - 20-mg-release-specifications	[Submission no.]